

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

GENETIC TECHNOLOGIES LIMITED,)	
)	
Plaintiff,)	
)	C.A. No. 12-1736-LPS
v.)	
)	
LABORATORY CORPORATION OF AMERICA)	
HOLDINGS, LABORATORY CORPORATION)	
OF AMERICA, and 23ANDME, INC.,)	
)	
Defendants.)	

**LABORATORY CORPORATION OF AMERICA HOLDINGS,
LABORATORY CORPORATION OF AMERICA, AND 23ANDME, INC.'S
REPLY BRIEF IN SUPPORT OF MOTION TO DISMISS**

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I. INTRODUCTION

The '342 Patent claims the discovery of a fact about the world – that the presence in the human body of two copies of a particular allele is “positively associated with potential sprinting, strength, or power performance.” United States Patent No. 7,615,342 (“’342 Patent”), claim 1. Defendants brought this motion to dismiss to resolve a simple, dispositive legal question: does Genetic Technologies Limited (“GTG”) have the legal right to own that fact about the world?

GTG tries a number of tactics to avoid confronting that basic legal question. It engages in a shell game in which it refuses to tell the Court which claims it is asserting against Defendants, then uses that refusal to argue that the Court has no jurisdiction to dispose of the case. It asserts that the Court must deny a motion to dismiss because there might be disputed facts or matters of claim construction, but it never tells the Court what those *disputed* facts or claim constructions might be. And when it finally does get to the merits, GTG falls back on mischaracterizing the law, to such an extent that it cites a controlling Supreme Court case for a proposition directly opposite to the one it stands for, and ignores entirely the Supreme Court decision that is directly on point.

There are no factual or claim construction disputes that prevent resolution of the simple legal issue at the heart of this motion. And there is no real dispute as to what the law requires.

II. LEGAL STANDARD

Patentable subject matter is a question of law. GTG calls this assertion “false” (twice), but the cases are quite clear on this point. *E.g.*, *In re Bilski*, 545 F.3d 943, 951 (Fed. Cir. 2008) (en banc) (“Whether a claim is drawn to patent-eligible subject matter under § 101 is an issue of law that we review de novo.”), *aff’d sub nom. Bilski v. Kappos*, 130 S. Ct. 3218 (2010); *AT&T Corp. v. Excel Commc’ns, Inc.*, 172 F.3d 1352, 1355 (Fed. Cir. 1999) (“whether the asserted claims of the ’184 patent are invalid for failure to claim statutory subject matter under 35 U.S.C.

§ 101, is a question of law which we review without deference”), *abrogated on other grounds by In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008); *SiRF Tech., Inc. v. Int’l Trade Comm’n*, 601 F.3d 1319, 1331 (Fed. Cir. 2010) (“Whether a patent claim is drawn to patent-eligible subject matter is an issue of law that is reviewed de novo.”); *Dealertrack, Inc. v. Huber*, 674 F.3d 1315, 1334 (Fed. Cir. 2012) (“Whether a patent claim is drawn to patent-eligible subject matter is an issue of law that is reviewed de novo.”). GTG tries to avoid the repeated, unequivocal statements of the law in over a dozen Federal Circuit cases by saying that in some of those cases the court must have made implicit factual determinations, even though it said it was deciding a legal question.¹ Plaintiff Genetic Technologies Limited’s Answering Brief in Opposition to Defendants’ Motion to Dismiss (“Opp.”) at 6-7. Indeed, it even claims that the court in *Cardpool, Inc. v. Plastic Jungle, Inc.*, No. C 12-04182 WHA, 2013 U.S. Dist. LEXIS 9280, at *4-5 (N.D. Cal. Jan. 22, 2013), made “factual determinations” in granting a 12(b)(6) motion. That does not prove that the courts are wrong when they say patentable subject matter is a question of law; if anything, it shows that GTG is wrong to argue that this Court can’t resolve patentable subject matter on a motion to dismiss.

There is, as GTG observes, a statutory presumption of validity in 35 U.S.C. § 282. But it is an *evidentiary* presumption (requiring proof by “clear and convincing *evidence*”), and it accordingly applies only to factual questions. It has no application to a pure question of law. *Microsoft Corp. v. i4i LP*, 131 S. Ct. 2238, 2253 (2011) (“In this area of law as in others the evidentiary standard of proof applies to questions of fact and not to questions of law.”)

¹ Occasionally facts or claim construction are in dispute and resolution of those disputes is necessary to understand whether the patent claims patentable subject matter. See *In re Comiskey*, 554 F.3d 967, 975 (Fed. Cir. 2009) (“there may be cases” that turn on subsidiary factual questions though not here); *Arrhythmia Research. Tech. v. Corazonix Corp.*, 958 F.2d 1053, 1055-56 (Fed. Cir. 1992) (some cases “may require findings of underlying facts” though not here). But, as discussed in more detail below, there are no such issues presented here.

(citing *Addington v. Texas*, 441 U.S. 418, 423 (1979)).

III. GTG CANNOT DODGE THE PATENTABLE SUBJECT MATTER QUESTION

A. GTG Has Identified No Disputed Fact or Claim Construction Questions

In an effort to avoid resolution of the simple question of law presented by Defendants' motion, GTG points to "factual assertions" which it says require evidentiary support. Since Defendants are precluded from offering such evidentiary support in a motion to dismiss, GTG argues, the motion must be denied.

GTG complains that Defendants have made a factual assertion that the "DNA sequencing," "hybridization," and related technologies included in claim 6 were "conventional steps" by 2003. But the patent itself identifies those methods as well-known in the art. *See, e.g.*, '342 Patent, at 8:67-9:3 ("A variety of hybridization assays using a variety of techniques for hybridization and detection are known in the art and any such known technique may be used. . ."); *id.*, at 11:1 ("Various forms of amplification are well known in the art . . ."); *id.*, at 13:52-55 ("Various methods for detection of nucleic acid sequence variants are known in the art and any such known method may be used [including hybridization].").

None of the other things GTG claims to be "facts" are any such thing. Whether the discovery of the relationship between the 577R allele and sprinting ability is a fact about the world, and whether taking a sample and analyzing it are "specified at a high level generality" are legal issues, not factual disputes, because they involve the scope of the claim and the definition of a law of nature. Whether claim 1 includes additional steps, and what prediction is, are things evident from the language of the patent claims and specification itself; even if they were in dispute, there would be nothing factual about that dispute.

The same problem bedevils GTG's argument that the motion cannot be resolved without construing the claims. It is true that claim construction may be helpful in some cases, though

“not an inviolable prerequisite to a validity determination under §101.” *Bancorp Servs., LLC v. Sun Life Assurance Co. of Canada*, 687 F.3d 1266, 1273-74 (Fed. Cir. 2012). But claim construction is required only where there is some dispute as to what the claims mean, and only where it would be helpful to resolve that dispute by substituting the words of the claim construction for the words of the claim itself. *E.g.*, *Biotec Biologische Naturverpackungen GmbH & Co. KG v. Biocorp, Inc.*, 249 F.3d 1341, 1349 (Fed. Cir. 2001) (finding no error in non-construction of “melting”); *Mentor H/S, Inc. v. Med. Device Alliance, Inc.*, 244 F.3d 1365, 1380 (Fed. Cir. 2001) (finding no error in court's refusal to construe “irrigating” and “frictional heat”). GTG’s claim construction argument is even more cursory than its factual issues argument. It doesn’t even purport to identify any claims in the patent that might require construction, much less anything in Defendants’ motion that suggests a particular construction of that term, whether or why GTG might disagree with that construction, or why any such disagreement might matter to resolution of the patentable subject matter issue.

“The purpose of claim construction is to ‘determin[e] the meaning and scope of the patent claims asserted to be infringed’ . . . [w]hen the parties raise an actual dispute regarding the proper scope of [these] claims . . .” *O2 Micro Int’l v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1360 (Fed. Cir. 2008). There is no such dispute here, and accordingly no reason to require claim construction to resolve this motion.

B. GTG Cannot Avoid Invalidity by Playing a Shell Game with Its Claims

In its complaint, GTG asserted claim 1 of the ’342 Patent. It now says that it may assert “one or more claims” but refuses to tell the Court which ones they are. Opp. at 8 n.3. Even if GTG is allowed to get away with not identifying the patent claims it thinks that Defendants infringe, it surely cannot argue that this Court has jurisdiction over the case but lacks jurisdiction to resolve the motion to dismiss. The jurisdiction of the federal courts is not like

Schrodinger's cat, existing in some indeterminate state in which there is both jurisdiction and lack of jurisdiction, waiting for GTG to open the box and tell us which claims it is asserting.

GTG sued Defendants for infringement of the '342 Patent. As to each claim in the patent, GTG is either alleging infringement of that claim or it isn't. On the one hand, if GTG is alleging infringement of that claim, this Court has subject matter jurisdiction with respect to it. *See, e.g., MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007) (standing requires only a live controversy between the parties). And if the claim is invalid as a law of nature, dismissal is appropriate because GTG has failed to state a claim on which relief can be granted. On the other hand, if GTG is **not** alleging infringement of a particular claim, dismissal of this suit is appropriate as to that claim for lack of subject matter jurisdiction.² Either way, as to both the asserted and unasserted claims, dismissal is the correct result.

IV. GTG'S CLAIMS ARE NOT PATENTABLE

Having endeavored for half of its brief to avoid addressing the single question presented in Defendants' motion, GTG finally does attempt to defend four of its claims – claims 1, 4, 6, and 9. Even then, most of its brief is devoted to an effort to avoid the clear import of *Mayo* and *PerkinElmer*.³

A. The Validity of Other Patents Is Irrelevant in This Case

GTG devotes fully five pages to listing claims of other patents it believes are similar in

² If GTG is *not* alleging infringement of a particular claim, GTG could divest the court of subject matter jurisdiction over that claim only by a clear and unequivocal commitment that it will not assert those claims against any current or anticipated future products. *Already LLC v. Nike, Inc.*, 133 S. Ct. 721 (2013); *Super Sack Mfg. Co. v. Chase Packaging Corp.*, 57 F.3d 1054 (Fed. Cir. 1995), *overruled on other grounds by MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007). Far from making any such commitment, GTG refuses to say which claims it might consider to be at issue in this case, though its decision to defend the validity of only four of the claims in its brief might give a hint.

³ *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012); *PerkinElmer, Inc. v. Intema Ltd.*, No. 2011-1577, 2012 U.S. App. LEXIS 23845 (Fed. Cir. Nov. 20, 2012).

nature to its claims that have recently been issued by the PTO. Those other patents are simply irrelevant to the issue before this Court. The PTO issues nearly 250,000 patents every year. When litigated to judgment, nearly half of those patents turn out to be invalid. John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185 (1998) (46% of patents litigated to judgment were held invalid). It is not a defense to a charge of invalidity that faithfully applying the law might render other patents invalid too. Nor is it a defense that because the PTO issued patents of a certain type, they must be valid. Were that true, there would never be any need for an invalidity proceeding in district court.

B. The Machine-or-Transformation “Test” Cannot Help GTG

GTG asserts that “a claimed method qualifies as statutory subject matter if (1) it is tied to a particular machine or apparatus or (2) it transforms a particular article into a different state or thing.” Opp. at 15-16. Remarkably, it cites *Bilski v. Kappos*, 130 S. Ct. 3218, 3225-26 (2010) for that proposition (“quoting *In re Bilski*, 545 F.3d 943, 954 (Fed. Cir. 2008)”). The Supreme Court decision in *Bilski* stands for no such proposition. To the contrary, the Court took the case precisely to *reject* the conclusion asserted by GTG that the presence of a machine or transformation established patent eligibility. *Id.* at 3226-27 (“Adopting the machine-or-transformation test as the sole test for what constitutes a ‘process’ (as opposed to just an important and useful clue) violates these statutory interpretation principles. . . . The machine-or-transformation test is not the sole test for deciding whether an invention is a patent-eligible ‘process.’”). And in *Mayo*, the Supreme Court made crystal clear that whatever value the machine-or-transformation inquiry had in deciding whether a patent was an abstract idea, proof of a machine or transformation could not save a claim that, like those at issue here, was directed to a product of nature:

[I]n stating that the “machine-or-transformation” test is an

“important and useful clue” to patentability, we have neither said nor implied that the test trumps the “law of nature” exclusion. *Bilski*, *supra*, at —, 130 S.Ct., at 3225–3227 (emphasis added). That being so, the test fails here.

Mayo, 132 S. Ct. at 1303. GTG neglects to mention *Mayo*’s holding that the machine-or-transformation test does not apply to laws of nature. Accordingly, while failure to meet the machine-or-transformation test might show that GTG’s claims were ineligible, meeting that test is *not* sufficient to declare a claim directed to a law of nature patentable subject matter.

In any event, were the test to apply, none of GTG’s claims could pass it. There is simply no “particular machine” to which any of those claims is tied. GTG argues that “each of these analysis methods [in claim 6] require the use of various machines.” Opp. at 17. But the claims themselves do not call out any machine at all, much less limit the claims to a “specific machine” as the test would require.

Nor do the claims “transform a particular article into another state or thing.” As to claims 1 and 9, GTG’s only assertion is that “predicting” whether someone is a likely sprinter “require[s] transformation of the information obtained.” But transformation of *information* is not what the machine-or-transformation test requires. It requires transformation of *an article* into a different *state or thing*. Even the Federal Circuit opinion in *Bilski*, the high-water mark of the transformation inquiry, made it clear that merely transforming abstract information was insufficient to satisfy the test. *Bilski*, 545 F.3d at 963-64. At most, “predicting the potential sprinting . . . of the human” transforms that human’s self-knowledge; after the prediction, the patient knows a fact about himself he didn’t previously know. That is even more abstract than the “transformation” of contracts for the sale of coal rejected as insufficient in *Bilski*.

Finally, GTG says that because claim 4 uses a man-made antibody to measure the amount of ACTN3, that claim is necessarily patentable even though that antibody is well-known in the

art.⁴ That cannot be correct. Were it so, any claim to a law of nature would be patentable as long as one conventional step of that claim used something man-made – a syringe to draw blood, a microscope to look at it, or a chemical to analyze it. The Supreme Court in *Mayo* held invalid claim 5 of U.S. Patent No. 6,255,623, which required measurement of a metabolization level “determined using high pressure liquid chromatography.” *Mayo*, 132 S. Ct. at 1305. That is surely a process using man-made tools, but the Court nonetheless found that it “[did] not differ significantly” from the claim to the process itself. Both claimed unpatentable facts about the world. *Mayo*, 132 S.Ct. at 1295.⁵

C. *Mayo* Confirms the Ineligibility of the Asserted Claims

All of GTG’s hand-waving about legal standards and nonexistent factual disputes, its curious argument about subject matter jurisdiction, and its lengthy focus on a machine-or-transformation test that has been rejected by the Supreme Court, are meant to obscure a single, remarkable fact: GTG has *no answer* to the fact that *Mayo* renders its claims invalid. None. We don’t mean that as a matter of rhetoric: that the answers aren’t very good, or don’t engage directly with Defendants’ arguments. We mean it literally. In its ten pages of discussion of the merits of Defendants’ motion – a motion premised first and foremost on *Mayo* – GTG does not discuss the language or the holding of the case at all. The only references to *Mayo* in the argument section are a reference to post-*Mayo* PTO guidelines, Opp. at 11, and a mention that

⁴ The fact that it is well-known is evident from the ’342 Patent at 15:22-25 (“Techniques for preparing and using various antibody-based constructs and fragments are well known in the art. Means for preparing and characterizing antibodies are also well known in the art.”).

⁵ GTG analogizes claim 4 to the one method claim upheld in *Myriad*. That claim was directed not to prediction or diagnostics, but to a method for testing a new therapeutic drug for efficacy against cancer that could result in actual treatment of breast cancer. The court relied on the identification and use of a new chemical in holding the claim patentable. *Assoc. for Molecular Pathology v. U.S.P.T.O.*, 689 F.3d 1303, 1336 (Fed. Cir. 2012), *cert. granted on other grounds*, *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S.Ct. 694 (2012). There is no similar new chemical or treatment here.

Mayo cited a nineteenth-century English case, *Opp.* at 17.⁶

There's a simple reason for that: GTG has no way to distinguish the holding in *Mayo*. *Mayo* holds that relationships between the level of a chemical in the human body and a medical outcome are "a law of nature." *Mayo*, 132 S. Ct. at 1296. *Mayo* holds that to be eligible, a patent must do "significantly more" than merely identify and describe the effects of those natural relationships. *Id.* at 1297. *Mayo* holds that telling a doctor or law to determine the level of a chemical in the body using existing methods does not avoid the law of nature limitation. *Id.* at 1297-98. *Mayo* holds that adding a step of having the doctor use the resulting knowledge to inform a patient about a circumstance or condition does not avoid the law of nature limitation. *Id.* at 1298. *Mayo* holds that "simply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable." *Id.* at 1300. *Mayo* holds unpatentable claims that "inform a relevant audience about certain laws of nature" where "any additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community" – precisely the situation here. *Id.* at 1298. *Mayo* holds the law of nature rule "cannot be circumvented by attempting to limit the use of the formula to a particular technological environment," *id.* at 1297, as GTG does in pointing to specific means of measuring the level of ACTN3 or identifying the 577R alleles using existing technology. And *Mayo* holds that a claim that would tie up the most logical uses of a newly-discovered natural law are unpatentable, *id.* at 1301, which disposes of claims 1 and 9 and the "predicting" and "selecting a training program"

⁶ GTG relies at length on that English case, which obviously is not binding precedent, to justify its claims. In fact, however, *Mayo* explains that the case holds that a process might be patentable when "the claimed process include[s] not only a law of nature but also several unconventional steps." *Mayo*, 132 S. Ct. at 1300. GTG does not offer even a hint as to what the "unconventional steps" in its patent might be; all the processes identified in claims 4 and 6 are well-known in the art, as its own patent acknowledges. *See supra* at 3, 8 n.4.

limitations.⁷

GTG's claims are precisely the sort of thing *Mayo* holds unpatentable. They analyze a gene sample from a patient using conventional technology, identify a relationship based on a newly-discovered natural law, and use that relationship to predict an outcome. That simply isn't patentable subject matter. This Court does not need to gather additional facts or construe claim terms to reach that result. It simply needs to apply *Mayo* – the one thing GTG hopes desperately to distract the Court from doing.

V. CONCLUSION

The motion to dismiss should be granted without leave to amend.

Respectfully submitted,

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⁷ The complaint is devoid of even the remotest suggestion that Defendants are in the business of “selecting a training program based on predicting potential sprinting.” That is because Defendants do no such thing, and GTG could not contend that they did consistent with its Rule 11 obligations.

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

CERTIFICATE OF SERVICE

I, David E. Moore, hereby certify that on March 25, 2013, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I further certify that on March 25, 2013, the attached document was Electronically Mailed to the following person(s):

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